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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,820	09/30/2003	Gary K. Michelson	101.0093-01000	6670

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EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/675,820

Applicant(s)

MICHELSON, GARY K.

Examiner

James L. Swiger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 31-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 31-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/29/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

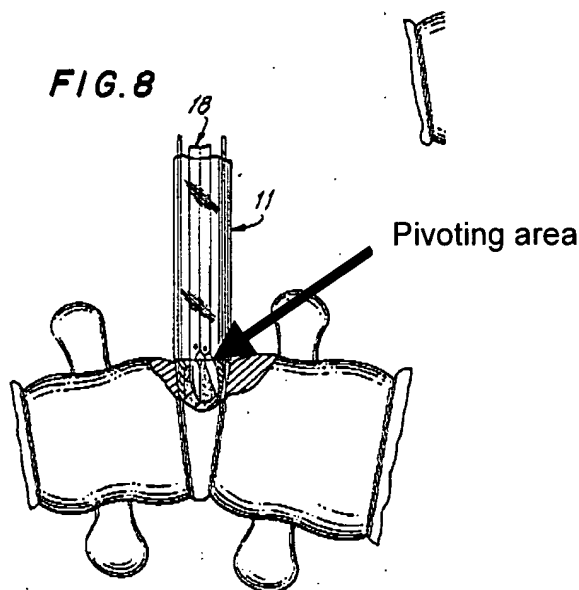
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson (US 4,545,374). Jacobson discloses a spinal device comprising a body (10) having a first end (that heads into the vertebral area) and a trailing end (opposite),

wherein the device has a pivotal relationship between the two portions (compare item 10 in Figs. 4 and 5; also element capable of pivoting in drawing).



The first and second portions are also at least partially arcuate (see Figs. 12 and 13) which define an opening and a disc-space therebetween that may also be considered generally circular. In both the open and closed positions, the first and second body portions (10 and 10) are generally parallel, both in the closed and open positions (see Figs. 4 and 5). The two portions are also adapted to allow for a surgical instrument to pass through, and that are also at least partially arcuate (see Fig. 8). Depending on the rotation of the device in use, the first and second portions may be oriented towards the adjacent vertebral bodies of the patient's spine. The disc space is also considered in view of the full length of the device as in forming a tube.

Jacobson also discloses a device that has a body that is generally oval and elliptical, and likewise may also be considered generally circular, along the length and also viewed as a cross section (Fig. 13).

Claims 1-19 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Cauthen (US Pub 2003/0135220). Cauthen teaches a guard for use in spinal surgery having a body (12), having a leading end (17) and opposite trailing end (15), the body having a first portion (18) and a second portion (37) in a pivotal relationship with one another (see figs. 13 and 14), the proximate leading end (17) having an open and closed position. The first (18) and second (37) portions have at least in part opposed interior arcuate portion (14), respectively, and wherein the first and second portions define an opening for providing access to the disc space, a space that may be considered a tube and is adapted to provide access and guide therethrough a surgical instrument. The opening defined by the first and second portions of the body is generally circular but may also be elliptical (see paragraph 0039). Also the body's exterior surface has opposed upper and lower surfaces that are in part arcuate as well; wherein the exterior surface of the body has opposed side surfaces that are also in part arcuate and generally parallel; these sides also generally provide and are capable of providing a circular or elliptical cross section when in both the open and closed positions. The device may also be considered angled in the open position, at any given point between fully closed and fully open. The first and second portions also cooperatively engage each other when in a closed position (refer to Fig. 12). Further Cauthen teaches first and second portions that move rotatably to one another via a hinge, as they are associated with one another (par. 0034). Cauthen further describes that the device is able to create a disc space, as an 'open position' because of the ability of the device to rotatably articulate, creating a height (par. 0012) and allowing

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other devices to pass through. This orientation is considered along the mid-longitudinal axis. The device may also be secured/locked (par. 0045, line 15), and also comprises a collar (26, par 0040). Cauthen also teaches a body opening that has a height between 6-24 mm (par. 0038). Note that as claimed the opening as required for an instrument is between 8-25mm. However the range for Cauthen's device is 6-24. Therefore the device of Cauthen, as it is smaller, would be able to work within the situation as claimed by the applicant, meeting the size constraints. Cauthen teaches an opening between 6-24mm and would by default be able to fit a device within the 8-20mm opening from the claimed invention. Further Cauthen teaches that the hollow tube may accommodate a bone removal device such as a reamer (disclosed in line 3 of paragraph 0038; or for an implant driver, also considered an insertion instrument (disclosed in lines 4-5 of paragraph 00390; or further a spinal implant (line 5 of paragraph 0039). With regards to the implant being partially bioresorbable, Cauthen further teaches that the spinal implant may be coated with a biocompatible material such as hydroxyapatite, which is inherently biocompatible/resorbable, as it has a similar chemical composition as human bone. The implant itself may also be made of a metal such as titanium (Par. 0042).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen

'220 in view of Gruskin et al. (US 2003/0023209). Cauthen discloses the claimed invention except for an implant that is incorporated with a material to prevent scarring. Gruskin et al. discloses a substance, namely a cross-linked polysaccharide having a positive charge that allows for the wound site to heal with less scarring. (See par. 0010). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of Cauthen an anti-scarring additive in view of Gruskin et al. to better allow the wound area to heal with less damage.

Claim 30 rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 in view of Mansourt et al. (US 2003/0229401). Cauthen discloses the claimed method of the spinal implant except for an implant having an antimicrobial agent. Mansouri et al. discloses an anti-microbe agent to prevent the colonization of bacteria on the surfaces of the implant or other parts of the device, or more specifically while treating a non-metallic medical device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of Cauthen an anti-microbial agent to prevent infection and a more successful surgical application. (par. 0010).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-

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5557. The examiner can normally be reached on Monday through Friday, 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 5/28/06

JLS


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER